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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/080,868 | 02/22/2002 | Kenneth A. Davis | P-4296P1C1 | 2601 |

7590 08/02/2004

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| EXAMINER |
|-------------------|
| SAUNDERS, DAVID A |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1644 | |

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|----------------------------|------------------------|
| Application No. 080,868 | Applicant(s) DAVIS |
| Examiner SAUNDERS | Group Art Unit 1644 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on 5/20/04.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- Claim(s) 1-13, 25, 27, 39-45, 51, 54 is/are pending in the application.
- Of the above claim(s) 1-13, 25, 27 is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 39-45, 51, 54 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- FILED 6/4/04
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 6/4/04
 - Interview Summary, PTO-413
 - Notice of Informal Patent Application, PTO-152
 - Notice of Reference(s) Cited, PTO-892
 - Other _____
 - Notice of Draftsperson's Patent Drawing Review, PTO-948

Office Action Summary

Claims 1-13, 25, 27, 39-45, 51 and 54 are pending.

Applicant's election without traverse of Group II (claims 39-45, 51 and 54) in the reply filed on 5/20/04 is acknowledged.

The disclosure is objected to because of the following informalities: applicant must update status of each of applications 09/406,013 (pg. 1) and 08/943,491 (pg. 22).

Appropriate correction is required.

Claims 39-4,5 51 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 39 and 51 recite new matter by reciting "for a cell surface molecule".

In the amendment of 2/22/02 applicant has urged that recitation of a generic "cell surface molecule" is supported in the paragraph spanning pages 31-32. While the office concurs that "cell surface molecule" is recited at page 32, line 2, it must be realized that this is to be taken in the context of what precedes in the same paragraph. Therein it is clear that applicant was not describing any and all "cell surface molecules" but, rather, those for which there is a "time dependence" (first two lines of para. spanning pages 31-32) of a signal obtained upon fluorescent antibody staining, and for which the signal can be stabilized over time (page 32, line 1) by chloroquine (lysotropic amine). By not this limiting the nature of "cell surface molecules" to this sub-genus, applicant has improperly broadened the scope of invention.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39-45, 51 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,200,766. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims have nearly the same text as those issued, except for the fact that the instant claims are drawn to compositions and kits in which the antibody is directed to a generic cell surface antigen found on peripheral blood cells, while issued claims are drawn to compositions and kits in which the antibody is particularly directed to an HLA_DR cell surface antigen. The instant claims clearly encompass those issued; thus a disclaimer is required to assure that common ownership will be maintained between Pat. 6,200,766 and any Patent issued from the instant application.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schneider et al. (cited on form 1449) teach radiolabelled antibodies directed against plasma membrane (cell surface) molecules. These labeled

antibodies are mixed with chloroquine or methylamine (page 33, col. 2). This teaching does not anticipate or render obvious the instant claims, since the stained plasma membrane molecules are on fibroblasts, not peripheral blood cells, and since the label is a radio isotope, not a fluorophore.

Kao et al (cited on 1449) show incubation of platelets with chloroquine and then washing of the incubated platelets; these are then indirectly stained with fluorescent-labeled antibodies. This does not anticipate or suggest the instant invention, since chloroquine is not mixed with antibody and since the labeled antibody is not directed against a cell surface antigen.

Michinto et al (cited on 1449) show a technique, similar to that of Kao et al, far staining HLA on neutrophils. For like reasons, this does not anticipate or suggest the instant invention.

Vayurelgula et al (cited on 892) teach incubation of purified peripheral blood T-cells with anti-CD3 antibody and chloroquine, (page 248, col. 2). The antibody is not labeled with a fluorophore. There is thus no anticipation or suggestion of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
July 9, 2004

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 162-1684